Environmental Assessment

1. Date: October 22, 2021

2. Name of Applicant/Notifier: Mitsubishi Gas Chemical Co., Inc.

3. Address:

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All communications on this matter are to be sent in care of Counsel for Notifier:

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4. Description of the Proposed Action

The action requested in this Notification is to permit the use of the Food Contact Substance (FCS), 1,3-benzenedicarboxylic acid, polymer with 1,3-benzenedimethanamine and hexanedioic acid (CAS Reg. No. 28628-75-3), as a non food-contact layer in multilayer food-contact applications where the FCS is separated from food by a food-contact polymer layer which is authorized of the intended use. The FCS will be used in contact with all food types, except those containing more than 15 percent alcohol, under FDA's Conditions of Use A ("High temperature heat-sterilized (*e.g.*, over 212°F)") through H ("Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use").[1] The FCS is not intended for use in contact with infant formula and human milk. The intended technical effect of the FCS is to act as an oxygen barrier, provide thermal stability, and enhance thermoforming properties. The level of isophthalic acid-MXDA units in the FCS improves the barrier performance of the layer under high humidity conditions.

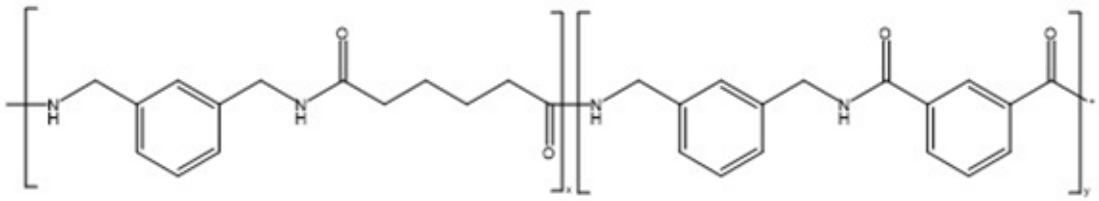
The Notifier does not intend to produce finished food-contact articles containing the FCS. Rather, the FCS that is the subject of this Notification will be sold to manufacturers engaged in the production of food-contact materials. Food-contact materials containing the FCS will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Therefore, it is anticipated that disposal of food-contact materials containing the FCS will occur nationwide, in quantities similar to those reported for municipal

[1] FDA's Food Types and Conditions of Use for FCNs are set forth at https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances.

solid waste generally.[2] According to U.S. Environmental Protection Agency (EPA) data for 2018, approximately 50.0% of municipal solid waste (MSW) is currently deposited in land disposal sites, 11.8% is combusted, 23.6% is recycled, 8.5% is composted, and 6.1% is directed to other food management pathways.[3] As the FCS is expected to be primarily disposed of through combustion or land-filling (*i.e.*, not recycled, composted, or handled through other food management pathways), we recalculate the disposal pattern based on only the quantities of MSW that are land disposed or combusted. On this basis, we estimate that 19.1% of food-contact materials containing the FCS will be combusted annually.[4]

5. Identification of the Substance that is the Subject of the Proposed Action

The FCS is 1,3-benzenedicarboxylic acid, polymer with 1,3-benzenedimethanamine and hexanedioic acid (CAS Reg. No. 28628-75-3). The FCS is a high molecular weight polymer, prepared by the condensation of 1,3-benzenedimethanamine (CAS Reg. No. 1477-55-0) with 1,3-benzenedicarboxylic acid (CAS Reg. No. 121-91-5) and hexanedioic acid (CAS Reg. No. 124-04-9). It is composed of the elements carbon, hydrogen, oxygen, and nitrogen. The chemical structure of the FCS is shown below.



The polymer is composed of 45 – 100 mol percent of 1,3-benzenedimethanamine-hexanedioic acid units ('x') and 0 – 55 mol percent of 1,3-benzenedimethanamine-1,3-benzenedicarboxylic acid units ('y').

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[2] *Advancing Sustainable Materials Management: 2018 Fact Sheet. Assessing Trends in Materials Generation and Management in the United States,* U.S. Environmental Protection Agency, Office of Land and Emergency Management, Dec. 2020, *available at* https://www.epa.gov/sites/production/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf.

[3] *Id.*

[4] By assuming that none of the FCS is recycled, we recalculate the fraction of FCS that is combusted as follows:

11.8% combusted ÷ (11.8% combusted + 50.0% land disposed) = 19.1% combusted. The remaining 80.9% will be land-disposed.

6. Introduction of Substances into the Environment

Under 21 C.F.R. § 25.40(a), an environmental assessment (EA) ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production of, FDA-regulated articles. Moreover, information available to the Notifier does not suggest that there are any extraordinary circumstances in this case indicative of any significant adverse environmental impact as a result of the manufacture of the FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No significant environmental release is expected upon the use of materials containing the FCS. In these applications, the FCS is expected to be entirely incorporated into the finished food-contact article. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed of as part of the food-contact article manufacturer's overall nonhazardous solid waste in accordance with established procedures. The annual projected market volume of the FCS is provided in the confidential attachment to the EA.

Disposal by the ultimate consumer of food-contact articles containing the subject FCS will be by conventional rubbish disposal, and, hence, primarily by sanitary landfill or incineration. For food-contact articles that contain the FCS that are determined to be recyclable, recycling processes will compete with conventional rubbish disposal and, therefore, reduce the amount of the FCS that is landfilled or incinerated. ASTM standard number D7611 "Standard Practice for Coding Plastic Manufactured Articles for Resin Identification" provides a guide for plastics manufacturers to mark the final plastic article with an identification code that informs users/recyclers of the identity of the resin with which the final plastic article is made.[5] We anticipate the articles manufactured with the FCS would be so marked and, thus, coded for recycling. However, we anticipate that food-contact articles manufactured with the FCS will not be recycled as most multilayer food packaging material is not typically recycled unless solvent-target recovery and precipitation is used.[6]

The FCS is composed of carbon, hydrogen, oxygen, and nitrogen. Thus, the combustion products of the FCS may include carbon dioxide and nitrous oxide. The carbon and nitrogen content of the FCS has been calculated based on the elemental composition of the FCS (available in the confidential attachment to the EA).

Greenhouse gas (GHG) emissions resulting from the use and disposal of the FCS relate to the incineration of articles containing the FCS in MSW combustion facilities. Such facilities are regulated by the U.S. Environmental Protection Agency (EPA) under 40 C.F.R. § 98.1, which "establishes mandatory greenhouse gas (GHG) reporting requirements for owners and operators of certain facilities that directly emit GHG." Part 2 of this regulation (40 C.F.R. § 98.2)

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[5] ASTM, Standard Practice for Coding Plastic Manufactured Articles for Resin Identification, 2020. D7611/D7611M-20.

[6] Theodore W. Walker, *et al*., *Recycling of multilayer plastic packaging materials by solvent-targeted recovery and precipitation*, SCIENCE ADVANCES, 20 NOV 2020: Vol. 6, No. 47 eaba7599, *available at* https://advances.sciencemag.org/content/6/47/eaba7599.

describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalent (CO2-e) emission threshold for required reporting.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to 40 C.F.R. § 1508.27, which defines 'significantly' as it relates to assessing the intensity of an environmental impact in National Environmental Policy Act (NEPA) documents. 40 C.F.R. § 1508.27(b)(10) states that, when evaluating intensity of an impact, one should consider "whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment." GHG emissions from MSW combustion facilities are regulated under 40 C.F.R. § 98.2. Further, the FCS will not significantly alter the emissions from properly operating MSW combustors. Therefore, incineration of the FCS will not cause MSW to threaten a violation of applicable emission laws and regulations (*i.e.*, 40 C.F.R. Part 60 and/or relevant state and local laws).

Based on the confidential market volume, the expected carbon dioxide equivalent emissions, as shown in the confidential attachment to the EA, are below 25,000 metric tons on an annual basis. As the estimated GHG emissions are well below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting from combustion of polymers containing the FCS in MSW combustion facilities. Further, the FCS will not significantly alter the emissions from properly operating MSW combustors as the FCS contains carbon, hydrogen, oxygen, and nitrogen, elements that are commonly found in MSW. Therefore, incineration of the FCS will not cause MSW combustors to threaten a violation of applicable emission laws and regulations (*i.e.*, 40 C.F.R. Part 60 and/or relevant state and local laws).

Only extremely small amounts, if any, of the FCS constituents are expected to enter the environment as a result of the landfill disposal of food-contact articles, in light of the EPA regulations governing municipal solid waste landfills. EPA's regulations require new municipal solid-waste landfill units and lateral expansions of existing units to have composite liners and leachate collection systems to prevent leachate from entering ground and surface water, "to have ground water monitoring systems and to take corrective action as appropriate (40 CFR Part 258)."

7. Fate of Emitted Substances in the Environment

A. Air

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the FCS. Because the FCS is a high molecular weight polymer, the FCS does not readily volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with the FCS.

As indicated above in Item 6, the FCS will make up a very small portion of the total municipal solid waste currently combusted. Therefore, combustion of the FCS will not significantly alter the emissions from properly operating MSW combustors, and the incineration of food-contact materials containing the FCS will not cause MSW combustors to threaten a

violation of applicable emissions laws and regulations. *See* confidential attachment to the EA for additional details.

B. Water

No significant effects on the concentrations of and exposures to any substance in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the FCS. The fate of finished food-contact articles containing the FCS in the aqueous environment does not need to be addressed because no significant introductions of substances into the environment were identified in Item 6.

C. Land

Considering the factors discussed above, no significant effects on the concentrations of and exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the subject FCS. In particular, the polymeric nature of the FCS is expected to result in virtually no leaching of components of the finished FCS under normal environmental conditions when these substances are disposed. Furthermore, the estimated production of finished food-contact articles with the FCS, as discussed in the corresponding confidential attachment to the EA, precludes any substantial release to the environment of its components. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the FCS.

Considering the foregoing, we respectfully submit that there is no reasonable expectation of a significant impact on the concentration of any substance in the environment due to the proposed use of the subject FCS in the manufacture of food-contact materials.

8. Environmental Effects of Released Substances

The only substances that may be expected to be released to the environment upon the use and disposal of food packaging materials fabricated with the subject polymer consist of small quantities of combustion products and leachables, if any. Thus, no significant adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the FCS. In conclusion, no information needs to be provided on the environmental effects of substances released into the environment as a result of use and/or disposal of the FCS because, as discussed under Item 6, only extremely small quantities, if any, of substances will be introduced into the environment as a result of use and/or disposal of the FCS. Therefore, the use and disposal of the FCS are not expected to threaten a violation of applicable laws and regulations, *e.g.*, EPA's regulations in 40 C.F.R. Parts 60 and 258.

9. Use of Resources and Energy

As is the case with other food packaging materials, the production, use, and disposal of the FCS involves the use of natural resources such as petroleum products, coal, and the like. The use of the subject polymer in the fabrication of food-contact materials is not expected to result in a net increase in the use of energy and resources, because polymers manufactured with the FCS are intended to be used in food-contact articles in place of similar polymers already on the market for use in food-contact applications. Polymers currently used in the applications in which

the FCS polymer is anticipated to be used include competitive polyamide oxygen barrier layer resins.

The partial replacement of this type of competitive material by the subject FCS is not expected to have any significant adverse impact on the use of energy and resources. Manufacture of the FCS, polymers containing the FCS, and the final conversion of the polymer to finished food-contact materials will consume energy and resources in amounts comparable to the manufacture and use of the other food-contact substances.

For these reasons, no significant adverse impacts on the use of natural resources and energy are expected as a result of this Notification becoming effective.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact materials fabricated using the subject FCS. This is primarily due to the minute levels, if any, of leaching of components of the FCS from finished articles employing the FCS, the insignificant impact on environmental concentrations of combustion products of the FCS, and the similarity of the subject FCS to the material it is intended to replace (*i.e.*, competitive polyamide barrier resins). Thus, no significant adverse impacts were identified that require mitigation measures.

11. Alternatives to the Proposed Action

No significant adverse environmental effects are identified herein that would necessitate alternative actions to those proposed in this Notification. The alternative of not approving the action proposed herein would simply result in the continued use of the material that the subject FCS would otherwise replace; such action would have no significant environmental impact.

12. List of Preparers

Cynthia B. Lieberman, B.A. Biology, J.D., Partner, Counsel for Notifier, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Over 13 years of experience counseling and representing corporate entities on FCNs, and assisting in the preparation of same, including EAs.

Steven J. Manning, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Dr. Manning has over five years of experience drafting FCN submissions and EAs.

13. Certification

The undersigned official certifies that the information provided herein is true, accurate, and complete to the best of her knowledge.

Date: October 22, 2021

[redacted]

Cynthia B. Lieberman
Counsel for Mitsubishi Gas Chemical Co., Inc.

14. References

1. FDA's Food Types and Conditions of Use for FCNs are set forth at https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances.

2. *Advancing Sustainable Materials Management: 2018 Fact Sheet. Assessing Trends in Materials Generation and Management in the United States,* U.S. Environmental Protection Agency, Office of Land and Emergency Management, Nov. 2020, *see* Advancing Sustainable Materials Management: 2018 Fact Sheet (epa.gov).

3. *Container Recycling Institute's Plastics Facts & Statistics* are available at http://www.container-recycling.org/index.php/factsstatistics/plastic.

4. ASTM, Standard Practice for Coding Plastic Manufactured Articles for Resin Identification, 2020. D7611/D7611M-20.

5. Theodore W. Walker, *et al*., *Recycling of multilayer plastic packaging materials by solvent-targeted recovery and precipitation*, SCIENCE ADVANCES, 20 NOV 2020: Vol. 6, No. 47 eaba7599.

15. Attachment

1. Confidential Environmental Attachment – Attachment 14